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GAO

Report to the Ranking Minority Member, Special Committee on Aging, U.S. Senate

October 1989

MEDICARE

Assuring the Quality of Home Health Services

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General Accounting Office
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Human Resources Division

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October 10, 1989

The Honorable John Heinz
Ranking Minority Member
Special Committee on Aging
United States Senate

Dear Senator Heinz:

In response to your request, this report addresses the Health Care Financing Administration's process for certifying home health agencies to participate in the Medicare program.

As you requested, we did not obtain official comments from the Department of Health and Human Services. Unless you publicly announce its contents earlier, we plan no further distribution of this report for 30 days. At that time, we will provide copies to the Secretary of Health and Human Services, the Director of the Office of Management and Budget, and other interested parties.

The major contributors to this report are listed in appendix II.

Sincerely yours,

Lawrence H. Thompson

Lawrence H. Thompson
Assistant Comptroller General

Executive Summary

Purpose

Medicare spending for home health services increased from $1.5 billion to an estimated $2.8 billion between fiscal years 1983 and 1989, and the number of agencies providing these services to Medicare beneficiaries increased by 43 percent to almost 6,100. This growth was accompanied by concerns that the Health Care Financing Administration's (HCFA) mechanisms for assuring the quality of home health services had not kept pace with the increasing number of agencies.

At the request of the Ranking Minority Member of the Senate Special Committee on Aging, GAO (1) reviewed the process HCFA uses to survey home health agencies and certify them to participate in Medicare and (2) identified matters it believes HCFA should address to ensure that the benefits sought by recent legislation concerning the quality of home care services are obtained.

Background

The Medicare home health benefit covers care provided Medicare beneficiaries in their homes. To ensure that beneficiaries receive quality home care, HCFA established standards that home health agencies must meet to participate in Medicare.

HCFA contracts with the states to conduct periodic surveys of home health agencies and determine whether they comply with HCFA's standards concerning the organization and operation of agencies. HCFA uses these surveys to certify that agencies are eligible to participate in Medicare.

Concerned that HCFA's certification process did not assure that Medicare beneficiaries received quality home health services, the Congress included provisions intended to strengthen that process in the Omnibus Budget Reconciliation Act of 1987 (OBRA). These provisions require that, in assessing the quality of care that home health agencies provide, states must measure how home health care has affected patient health. Further, the provisions authorize HCFA to use new sanctions to enforce home health standards, and establish additional standards. HCFA is developing regulations and other guidance to implement the OBRA provisions.

Also, the Medicare Catastrophic Coverage Act of 1988 requires HCFA to develop standards for organizations that provide intravenous drug therapy (a high-technology medical service) in the home, including training standards for personnel who provide the service.

Results in Brief

HCFA's guidance on the methods for conducting state surveys of home health agencies has not ensured that surveyors use sound methods to (1) sample the patient records they review and (2) interpret Medicare standards consistently in order to present an accurate picture of home health agency performance. HCFA also has not given the states pertinent information gathered by its claims processing contractors and peer review organizations for use in assessing compliance with Medicare standards.

HCFA is developing training standards for personnel who provide high-technology treatments to Medicare beneficiaries in their homes. However, current law does not require HCFA to develop training standards for all such personnel.

Through OBRA, the Congress revised many aspects of the home health agency certification process with the goal of improving the quality of home care. The next step toward that goal is for HCFA to give home health agencies and the states specific direction for implementing these revisions through regulations and procedural guidance.

Principal Findings

Implementation of OBRA Will Strengthen Home Health Agency Certification Process

OBRA requires that state certification surveys include measures of how the home health agency services affect patient health status. It also requires that state surveys include visits to patients' homes. HCFA would assist the states in implementing these provisions by issuing guidance that specifies the data needed to measure how care affects patient health, the data to be collected from patients in their homes, the criteria for identifying substandard care, and procedures for selecting patients for home visits. (See pp. 15-16.)

OBRA strengthens enforcement of home health standards by providing HCFA a range of sanctions to impose on agencies found in noncompliance with these standards. Regulations and guidance that specify the conditions that warrant imposing the sanctions OBRA authorizes would contribute to consistent and fair administration of these sanctions. (See p. 17.)

Guidance on Survey Methods and Rating Agency Performance Needs Improvement

HCFA's current guidance to states does not ensure that the surveys present an accurate picture of home health agency performance. For example, review of patient clinical records is an important source of information on agency performance. GAO reviewed 44 state surveys and found that the sampling methods used to select patient records often were not sound. Specifically,

- in 28 cases surveyors could not be certain that their sample was impartial because they had allowed home health agency staff to select patient records for reviews, and
- surveyors sometimes concluded that an agency's services met Medicare standards even though the records sampled sometimes did not cover all the services an agency provides.

GAO noted that different state surveyors interpreted the Medicare standards for home health agencies in different ways. HCFA needs to give the states guidance on how to measure the degree of compliance with each home health agency standard to assist them in arriving at consistent conclusions about agency performance. (See pp. 25-27.)

HCFA does not give the states data that its claims processing contractors and peer review organizations develop during their reviews of similar areas of home health agency performance. Also, HCFA regional offices do not fully analyze existing data on survey results to assess how well the states conduct surveys. (See pp. 27-29.)

Regulation of High-Technology Treatment Training Is Incomplete

Increasing numbers of Medicare beneficiaries are receiving high-technology medical treatments in their homes. Although the Medicare law gives the Secretary of Health and Human Services (HHS) general authority to regulate providers of home health services in the interest of beneficiary health and safety, HCFA's standards for home health agencies do not address the qualifications of persons who provide high-technology treatments. The health care authorities with whom GAO discussed one high-technology therapy said that home health agencies should require specific training and experience for personnel who provide the therapy. The eight home health agencies that GAO visited, however, did not consistently document the qualifications of their personnel who provided this therapy. (See pp. 31-33.)

OBRA and the Medicare Catastrophic Coverage Act of 1988 require that trained personnel be used in providing specified high-technology services. The OBRA provision, however, applies only to medical equipment

supplier personnel, and the Catastrophic Coverage Act provision applies only to persons providing intravenous drug therapy. Thus, the training standards would not apply to all persons who provide high-technology treatments in the home. (See pp. 18-19.)

Recommendation to the Congress

GAO recommends that the Congress amend the Social Security Act to require the Secretary of HHS to develop and enforce training standards for all persons who perform high-technology medical procedures in the home that present a risk to Medicare beneficiaries. (See p. 36.)

Recommendations to the Agency

GAO is making several recommendations to the Secretary of HHS to strengthen HCFA's guidance to the states for conducting home health agency surveys and to improve its management of the states' survey activities. (See pp. 35-36.)

Agency Comments

As agreed with the requester, GAO did not obtain official agency comments on a draft of this report. However, the views of responsible officials were sought and are incorporated in the report where appropriate.

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Abbreviations

GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
OBRA	Omnibus Budget Reconciliation Act of 1987

Chapter 1

Introduction

Medicare spending for home health services increased from $1.5 billion to an estimated $2.8 billion between fiscal years 1983 and 1989, while the number of agencies providing these services to Medicare beneficiaries increased by 43 percent to almost 6,100. This growth was accompanied by concerns that the Health Care Financing Administration's (HCFA) mechanisms for assuring the quality of home health services had not kept pace with the increasing number of agencies. As requested by the Ranking Minority Member of the Senate Special Committee on Aging, we examined the process HCFA uses to survey home health agencies and certify them to participate in Medicare. We also identified issues that we believe should be addressed in implementing recent legislation intended to improve home health care quality.

Medicare Home Health Care

Medicare, the federal health program authorized by title XVIII of the Social Security Act (42 U.S.C. 1395), pays for much of the health care costs for eligible persons 65 years old or older and certain individuals under 65 who are disabled or have chronic kidney disease. HCFA, an agency of the Department of Health and Human Services (HHS), administers the Medicare program. One Medicare benefit—home health services—provides care to a beneficiary who is confined to his home,[1] under a physician's care, and in need of part-time or intermittent skilled nursing care or physical or speech therapy. In addition, the home health benefit may cover the cost of

- services to help patients and their families adjust to social and emotional conditions related to the patient's health problems,
- part-time or intermittent home health aide services,[2] and
- certain medical supplies and appliances.

Medicare home health services can be furnished by a Medicare-certified home health agency or by others under contractual arrangement with such an agency. For a home health agency to participate in the program, HCFA must determine that the agency meets certain conditions of participation outlined in HCFA regulations.

[1]The Omnibus Budget Reconciliation Act of 1987 defined the term "confined to his home" as a "... normal inability to leave home, [such] that leaving home requires a considerable and taxing effort by the individual, and that absences of the individual from home are infrequent or of relatively short duration, or are attributable to the need to receive medical treatment."

[2]Home health aides help patients bathe, groom, get into and out of bed, use the bathroom, take self-administered medications, exercise, and perform other daily activities.

Medicare spending for home health services has grown, reaching an estimated $2.8 billion for about 42.6 million home visits in fiscal year 1989. The number of agencies certified to participate in the Medicare program likewise increased by about 43 percent between fiscal years 1983 and 1989, totaling almost 6,100 in fiscal year 1989, as seen in table 1.1.

Table 1.1: Information on the Medicare Home Health Program (Fiscal Years 1983-89)

Fiscal year	Expenditures (billions)	Visits (millions)	Patients served (millions)	Medicare-certified agenices
1983	$1.5	35.7	1.3	4,257
1984	1.9	39.7	1.5	5,275
1985	2.2	39.8	1.4	5,823
1986	2.3	39.8	1.4	5,965
1987	2.5	40.7	1.4	5,875
1988[a]	2.6	41.6	1.4	5,980
1989[a]	2.8	42.6	1.4	6,085

[a]HCFA estimates.

With the increased number of home health agencies, concerns were expressed in congressional oversight hearings about HCFA's ability to assure the quality of home care services. Responding to these concerns, the Congress incorporated a number of provisions intended to ensure the quality of home care services into the Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203, Dec. 22, 1987, hereafter referred to as OBRA). HCFA is developing regulations to implement these provisions and in August 1989 issued an interim final rule to establish certain new standards for home health agencies.

The Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360) also addressed home health care quality. The act provides coverage of intravenous drug therapy provided in the home and requires HCFA to develop standards for the therapy, including training standards for personnel who provide the therapy.

Medicare home health services differ from the home care financed under the Social Services Block Grant and the Older Americans Act. These programs emphasize supportive services, including homemaker and chore worker services, rather than the medical services covered by Medicare. The extent of home care under these programs is not clear because the programs have required limited reporting on the services provided.

The Survey and Certification Process Before OBRA

The Medicare law has historically authorized HCFA to establish minimum health and safety requirements for home health agencies that participate in the Medicare program. Referred to as conditions of participation, these requirements cover such areas as acceptance of patients, medical supervision, skilled nursing services, and maintenance of patient records. These conditions of participation are generally further explained by subordinate requirements, or standards. For example, two standards explain the condition of participation concerning the skilled nursing services that home health agencies provide; these standards address the activities of registered nurses and licensed practical nurses.

HCFA provides the states with funds to survey home health agencies and to recommend to HCFA whether it should certify the agencies as having complied with its conditions of participation. HCFA annually negotiates an agreement with a state agency—usually a component of the state health department—to survey various types of health care facilities, including home health agencies, skilled nursing facilities, hospices, and laboratories.

To assist state personnel in performing these surveys, HCFA has issued guidelines interpreting the conditions of participation and has conducted training courses for state surveyors. The state surveyors—most of whom have some background in health care—visit home health agencies to examine organizational, financial, personnel, and patient records to determine whether the agencies comply with federal requirements.

Based on the surveys, the state agencies determine whether a home health agency is in compliance with the Medicare conditions of participation. When surveyors note deficiencies in a home health agency's operations, the home health agency must develop and submit a plan of correction to the state. If a home health agency fails to achieve compliance with the conditions of participation, HCFA can terminate its participation in Medicare.

To improve home health surveys HCFA, in 1985, authorized surveyors to visit patients in their homes. In early 1987, HCFA awarded a contract to a consulting firm to review the existing survey process and identify ways in which state surveyors could better determine the quality of home care. The contract also provided for the consultant to (1) develop survey forms for conducting home visits, (2) prepare revised instructions for state surveyors, and (3) pilot-test the revised forms and instructions.

In 1985, HCFA also began to study whether accreditation by private organizations could be evidence enough that agencies have complied with the Medicare conditions of participation. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[3] and the National League for Nursing[4] expressed interest in having the home care programs that they accredit considered as having met the Medicare conditions of participation. HCFA developed a proposal to recognize the accreditation programs of these two organizations as a basis for certifying home health agencies to participate in Medicare. HCFA officials responsible for this proposal told us that they have deferred final action on it indefinitely.

Objectives, Scope, and Methodology

Objectives

This report addresses two congressional requests. Initially, the Ranking Minority Member of the Senate Special Committee on Aging requested us to review HCFA's process for certifying home health agencies to participate in Medicare. Accordingly, we examined HCFA's standards for certifying home health agencies and assessed

- HCFA's guidance to state survey agencies and
- the adequacy of state surveys of home health agencies.

After the enactment of OBRA, the Ranking Minority Member asked us to identify issues that HCFA should address in implementing the act. (See app. I.) To identify these issues, we compared OBRA provisions addressing home health agency certification with the work we had done during our examination of the certification process.

Chapter 2 of this report discusses the issues that we believe HCFA should address when developing implementing regulations and instructions for OBRA; chapter 3 discusses other areas in which our review indicated that

[3]Formerly known as the Joint Commission on the Accreditation of Hospitals, JCAHO is a private, nonprofit organization that conducts voluntary accreditations of hospitals and other health care facilities.

[4]The National League for Nursing is a private, nonprofit organization that seeks to promote quality nursing service and foster effective educational preparation of nurse practitioners. Through its Community Health Accreditation Program, the League conducts voluntary accreditations of community health and home health organizations.

HCFA needs to provide additional guidance to the states for carrying out home health agency certification surveys.

Scope

We did our work at HCFA's headquarters in Baltimore; at its regional offices in Atlanta, Boston, Philadelphia, and San Francisco; and at the state survey agencies and selected home health agencies in four states—California, Florida, Massachusetts, and Pennsylvania. These states were selected because (1) they provided a geographic mix, (2) their residents make substantial use of Medicare home health care, and (3) they account for a sizable percentage of the nation's Medicare-certified home health agencies. About 30 percent of Medicare home health visits are made to beneficiaries in these four states. About 16 percent of all Medicare-certified home health agencies are located in these states.

To obtain their views on the qualifications needed by medical personnel who perform one home health care service that was of particular interest to the requester—infusion therapy[5] —we interviewed representatives of the American Medical Association, JCAHO, the National Association for Home Care, and the National League for Nursing.

We reviewed laws, regulations, and other guidance pertaining to home health agency certification and held discussions with HCFA headquarters and regional officials concerning the certification process and their role in overseeing the states' survey activities. In each of the four states selected for review, we

- visited the state survey agency, reviewed guidance and other documentation concerning the home health agency survey process, held discussions with officials involved in the survey process, and examined in detail survey documentation and other records related to surveys conducted at 11 home health agencies; and
- visited two home health agencies that provided infusion therapy services, reviewed agency records, and held discussions with agency officials and a sample of nurses employed at the agency.

The 44 home health agency surveys (11 in each of the four states) provided a mix of agencies based on size (the number of Medicare-reimbursed visits by each agency). However, our selection always

[5]Infusion therapy involves nutritional support, administered either intravenously or through a soft tube placed in the stomach or intestine, as well as intravenous administration of antibiotics, chemotherapeutic agents, and various other drugs and fluids.

included the most recent survey of the home health agency in each state that had the largest number of Medicare-reimbursed visits. Included among the 44 agencies were 4 in each state with deficiencies on prior surveys. We included these agencies in order to determine whether surveyors devoted additional attention to areas in which deficiencies had been found in previous surveys. The 44 agencies also represented (1) various ownership types (visiting nurse associations, proprietary agencies, governmental agencies, etc.), (2) agencies that employed contract personnel, and (3) agencies for which surveyors had visited patients' homes.

Our selection of eight agencies that provided infusion therapy (two in each of the four states we reviewed) was based on contacts we made with hospitals and with knowledgeable officials in the states. Since we could not readily obtain information as to which agencies provided infusion therapy, we obtained the names of the agencies where hospitals referred patients needing home infusion therapy. From this list of agencies, we judgmentally selected two we would visit in each state.

Methodology

To assess HCFA's standards for certifying home health agencies to participate in the Medicare program, we

- reviewed the Medicare conditions of participation and interpretive guidelines and discussed them with HCFA and state officials and
- obtained opinions from representatives of national health organizations on the qualifications needed by personnel who perform one high-technology home care service—infusion therapy—and visited eight selected home health agencies in the states reviewed to develop a profile of the qualifications of a sample of personnel performing infusion therapy at these agencies.

To assess HCFA's guidance to state agencies and the adequacy of state surveys of home health agencies, we

- reviewed the survey reports and related documentation for 44 home health agencies and discussed in detail with state surveyors the scope and nature of their work;
- reviewed HCFA guidance and discussed survey practices with state officials concerning the methodology for conducting state surveys, particularly the (1) methods used to select patient records for review and (2) number of patient records reviewed;

- compared HCFA survey guidelines and instructions for performing surveys with those of JCAHO and HCFA guidelines for nursing home surveys;
- reviewed HCFA guidance regarding the coordination of Medicare fiscal intermediary and peer review organization activities relating to home health agencies with those of state survey agencies; and
- discussed with HCFA officials the agency's oversight of state survey agencies, particularly their use of statistical summaries of state performance, their surveys of home health agencies, and HCFA's annual evaluations of state survey agencies.

Our work was performed between July 1986 and February 1989 in accordance with generally accepted government auditing standards, except that, as agreed with the requester, we did not obtain agency comments on a draft of this report. The views of responsible agency officials were sought during our work and are incorporated where appropriate.

Chapter 2

Considerations for Implementing OBRA's Home Health Quality Provisions

As requested, this chapter describes selected OBRA provisions that address home health quality and provides our views on actions we believe HCFA could take to ensure that the benefits OBRA sought to achieve are obtained. Through its oversight of Medicare's home health benefit, the Congress became concerned that HCFA did not have adequate mechanisms in place to monitor and enforce compliance with its home heath agency standards and that additional standards were needed. Accordingly, the Congress included provisions in OBRA to strengthen the quality of home care services. Among these were provisions that

- required that surveyors measure the impact of home health care on patient health in order to evaluate the quality of care,
- required that surveyors visit patients' homes to obtain information on the quality of care,
- gave HCFA a range of sanctions to impose on home health agencies that did not comply with home health standards,
- required that each agency be surveyed at least every 15 months,
- established a new condition of participation that requires home health agencies to protect the rights of their patients, and
- required the Secretary of HHS to develop training standards for medical equipment supplier personnel.

The data gathered during our review gave us insight into some steps HCFA might find useful in implementing these provisions.

Quality-of-Care Measures in Home Health Agency Surveys

To shift the focus of surveys away from agency administration and toward patient outcomes, the Congress directed through OBRA that quality-of-care measures based on patient outcomes should be a routine component of surveys. During a survey, state surveyors must evaluate whether the care the home health agency provides enables beneficiaries to achieve the highest practicable health status. The states must also measure quality of care using indicators of medical, nursing, and rehabilitative care. When the states detect substandard care, the act requires a review of agency administrative records to identify the policies and procedures that resulted in the substandard care and to determine whether the agency complies with the Medicare conditions of participation.

GAO Comments

Based on experience gained during our review of the certification process, we believe HCFA could take a number of steps that would help state surveyors evaluate the quality of home care through patient outcome

measures. First, HCFA could specify the data needed to measure outcomes, such as patient health status when entering the agency's care, goals for progress as a result of care, and changes in health status during care. Guidance for surveyors could also include guidelines for use in detecting the delivery of substandard care and the deterioration in health status due to substandard care. Because determinations concerning the quality of care involve medical decisions, HCFA may also want to consider directing the states to provide appropriate medical supervision when these determinations are made by nonphysician surveyors.

HCFA might also consider directing home health agencies to furnish surveyors aggregate data they could use as broad indicators of the quality of care provided by agencies. Such data would include the proportion of agency patients who die, or require admission to a hospital or nursing home, shortly after treatment. Because diagnostic and demographic factors affect the risk of death or reinstitutionalization, the data could be reported in categories that would permit analyses to assess the quality of care. HCFA has published similar data for hospitals and has stated that while the data cannot be used for reaching final judgments about quality, they are valuable as a basis for asking questions about the quality of care and identifying potential problems.

Visits to Patient Homes During Home Health Agency Surveys

OBRA requires that surveyors routinely visit patient homes to evaluate home health care. A major change to the survey process that OBRA directed was to shift the survey emphasis away from a test of compliance with administrative and procedural requirements toward a meaningful evaluation of the care being provided. Home visits were required so that surveyors would obtain firsthand information regarding the nature and quality of care provided by home health agencies.

GAO Comments

Discussions with state surveyors during our review of the certification process indicate that detailed HCFA guidance is needed to ensure that (1) surveyors visit a large enough sample of patients to provide a realistic assessment of quality of care, (2) the services provided to these patients are representative of all the services an agency offers, and (3) the surveyors gather data concerning both the health status and the treatments provided to each patient. Such guidance could direct surveyors to confirm through discussions with the patients or their families that services recorded in patient clinical records have actually been performed. HCFA might also consider requiring that patients currently under care and those who have recently completed care be visited to ensure

that observations are made of the care being provided and its impact on patients' health.

Enforcement of Home Health Agency Certification Standards

To give HCFA flexibility to enforce home health quality standards, the Congress established through OBRA a range of sanctions other than termination for home health agencies, including (1) suspension of Medicare payments, (2) civil money penalties, and (3) appointment of temporary management for the home health agency. The act directs HCFA to develop specific procedures that set forth the circumstances under which these sanctions will be applied, minimize the time between identification of deficiencies and imposition of sanctions, and provide progressively more severe sanctions for repeated or uncorrected deficiencies.

GAO Comments

We believe that HCFA should specify in its implementing regulations those circumstances of noncompliance that warrant imposition of these sanctions. Such regulations could, for example, (1) specify the range of sanctions that may be applied in the event of noncompliance with each standard, (2) establish a means for measuring the frequency and severity of noncompliance as a basis for selecting the sanction to apply in a particular case, (3) establish criteria for determining when more severe sanctions should be imposed on agencies having a history of repeated noncompliance, and (4) establish specific time frames between the identification of deficiencies and imposition of the sanction.

Frequency of Home Health Agency Surveys

To assure that HCFA obtains timely information on home health agency performance, the Congress required through OBRA that each agency be surveyed at least every 15 months and directed HCFA to ensure that the average time between surveys in a state shall not exceed 12 months. Moreover, the act provides that an agency must be surveyed within 2 months of the reporting of a significant number of complaints to cognizant officials or organizations and may be surveyed within 2 months of any change in ownership, administration, or management.

GAO Comments

HCFA could help assure that the states meet the OBRA requirements by establishing a procedure to monitor state compliance with this provision, using data that the HCFA management information system for state surveys currently accumulates. Within the limits provided in the act, HCFA might consider requiring more frequent surveys of agencies found

to have provided substandard care in order to confirm that such agencies have taken action to improve the care they provide.

Protection of Home Health Agency Patient Rights

The Congress concluded that many homebound individuals did not fully understand Medicare's home health service coverage. Accordingly, the Congress established through OBRA a new Medicare condition of participation that requires home health agencies to (1) inform patients of the care they will receive and of any changes planned in their care, (2) inform patients of the coverage available for services under Medicare and other programs and of any charges they will have to pay, and (3) encourage patients to express grievances without fear of reprisal.

GAO Comments

HCFA guidance to state surveyors should be revised to require surveyors to examine how agencies have implemented these new patient rights protections. In our experience, guidance that identifies the records and documentation that should be examined to verify compliance with a requirement is helpful to state surveyors. Accordingly, HCFA might consider providing agencies model documents for advising beneficiaries of their rights as home health care patients.

Regulation of Services Provided by Medical Equipment Supplier Personnel

To address the qualifications of medical equipment supplier staff, the Congress amended the Medicare law to authorize the Secretary of HHS to develop training standards for personnel who demonstrate or use medical equipment.

The Medicare Catastrophic Coverage Act of 1988 addressed one high-technology medical service. The act's standards with respect to home intravenous drug services apply to any organization that provides a specific therapy rather than to one class of providers, as is the case under the OBRA home health agency provisions. The act made intravenous drug therapy provided in the home a covered benefit under Medicare and established standards for drug therapy providers. Among these standards are requirements that providers ensure that the staff performing drug therapy are adequately trained and that personnel who provide services under arrangements with a qualified provider are also adequately trained.

GAO Comments

The Secretary has long had general authority to regulate the qualifications of personnel who provide high-technology medical treatments in

the home. Taken together, OBRA and the Catastrophic Act give the Secretary specific authority to regulate the qualifications of some, but not all, such personnel. OBRA covers medical equipment supplier personnel, regardless of the equipment they use in home treatment; the Catastrophic Act covers persons providing intravenous drug therapy in the home, regardless of the organization that employs them. Therefore, persons employed by an organization other than a medical equipment supplier—a home health agency or a hospice, for example—who provide a treatment other than intravenous drug therapy—nutritional support or respiratory care, for example—are not required to receive training under either act or any HCFA regulation. We discuss information on the qualifications of certain personnel who fall into this coverage gap in chapter 3.

As a first step toward implementation of this OBRA provision, HCFA should identify those therapies that, because of their complexity, can present a risk to Medicare beneficiaries when performed in the home. Instructions to implement the provision would then (1) identify the classes of medical equipment used in these therapies that must be demonstrated by individuals who have specialized training to assure safe and effective use by patients or that must be used by persons having special skills or training to assure safe treatment and (2) specify the types of training or experience required of individuals demonstrating or using each class of equipment.

Under the amended OBRA provision, HCFA's claims processing contractors will be required to determine whether suppliers under their jurisdiction comply with the training requirements. To assist its contractors in making these determinations, HCFA should prepare instructions that address (1) how often contractors should verify that supplier personnel have met the training standards and (2) what documentation suppliers should maintain to demonstrate that their staff have met the standards.

HCFA Is Developing Regulations to Implement OBRA Provisions

HCFA is pursuing various actions to implement the OBRA provisions discussed in this chapter. As of August 1989, HCFA had issued an interim final rule to incorporate standards concerning patient rights but had not published regulations to implement the other provisions we discussed.

Concerning the OBRA provisions that require visits to patient homes, HCFA awarded a contract to a consulting firm in 1988 to develop survey forms and surveyor instructions. When the consulting firm completes and field-tests the new forms, HCFA plans an expanded field test using

either HCFA or state survey personnel. Upon completion of the expanded field test, HCFA plans to begin developing changes to regulations and other guidance to state surveyors needed to implement the revised survey process.

Concerning the OBRA provisions that strengthen HCFA's enforcement of home health standards by authorizing additional sanctions and specifying survey frequency, HCFA staff expect to publish a notice of proposed rulemaking in October 1989. Once these regulations are in place, HCFA will consider what changes to internal procedures and to its guidance to state survey agencies are needed to complete implementation of the provisions.

Regulations to incorporate the standards concerning patient rights that OBRA established for home health agencies were issued on August 14, 1989. Regarding standards for the training of persons who demonstrate and use medical equipment in the home, HCFA has held discussions with representatives of the elderly and the medical equipment industry and, as of August 1989, is in the first stage of drafting regulations.

Guidance on Survey Methods and Regulation of High-Technology Home Care Should Be Improved

OBRA gives HCFA legislative authority and specific direction that should strengthen the certification process for home health services. We found additional areas in which HCFA could, within its existing authority, strengthen its guidance for state surveyors and improve state survey practices. Current state survey practices cannot be relied on to provide an accurate and consistent picture of home health agency performance because HCFA has not given surveyors sufficient guidance on proper survey methodology. In reviewing a sample of surveys conducted in the four states visited, we found that surveyors did not use sound statistical techniques to select home health agency records for review. Further, surveyors did not appear to have a clear understanding about what evidence was needed to demonstrate compliance with the Medicare conditions of participation and what conditions indicated noncompliance.

Medicare claims processing contractors and peer review organizations conduct examinations of patient records that include areas similar to those examined by state survey agencies. HCFA, however, has not taken steps to see that the results of these examinations are shared with state survey agencies.

Increasing numbers of Medicare beneficiaries are receiving high-technology services in the home. HCFA's standards for home health agencies do not address the qualifications of persons who provide high-technology services—such as infusion therapy—in the home. As discussed in chapter 2, recent legislation has addressed the qualifications of such personnel, but does not cover all personnel who might provide high-technology treatments in the home.

HHS Study Raises Concerns About Quality of Home Health Care

HCFA normally expects state surveyors to compare plans of care for home health agency patients to clinical records and verify that

- required services are performed,
- home health agencies provide proper supervision to home health aides, and
- services provided by contract personnel are consistent with the plan of care.

The findings in a September 1987 report by the HHS Inspector General, Home Health Aide Services for Medicare Patients, raise serious questions about whether state surveys can be relied upon to ensure that Medicare patients receive quality home health care. According to the study:

- A review of patient records revealed that where plans of care called for home health aides to provide specialized services in support of care by skilled nurses or physical therapists, the aides failed to document and perform half of these tasks. This lack of care deprives the Medicare patient of full home care, resulting in a possible decreased potential for rehabilitation or increased chance of rehospitalization.
- Poor supervision of home health aides is the principal cause of less-than-adequate care. Substantial weaknesses were found in supervisory nurse orientation of aides in the manner in which they were to address patient needs.
- Aides under contract to agencies did not perform the majority of skilled care tasks assigned to them.

Guidance on Survey Methodology Is Not Adequate

HCFA's State Operations Manual and the accompanying Interpretive Guidelines for home health agency conditions of participation contain the guidance state surveyors use to examine and evaluate agency operations. However, these documents do not provide surveyors with enough guidance on survey methodology to ensure that the surveys validly reflect agency performance. The guidance does not require surveyors to use statistical techniques to select record samples for review that are representative of agency performance. In reviewing a sample of 44 agency surveys conducted in the four states visited, we found that individual surveyor sampling practices vary widely. We also found that guidance does not sufficiently emphasize surveyor control over the sampling process; many surveyors allowed agency personnel to select the patient records to review.

Inadequate Guidance on Selecting Records for Review

HCFA guidance directs surveyors to review patient records to evaluate the care an agency's skilled nurses, physical therapists, occupational therapists, speech therapists, medical social workers, and home health aides provide. The guidance does not, however, direct surveyors to select records randomly or use a sampling plan that would ensure valid results from record reviews. In many cases, surveyors reviewed so few patient records that there was little likelihood of obtaining a reliable indication of agency performance.

In addition to reviewing patient records, HCFA guidance directs surveyors to review many types of administrative records, including (1) agency organization charts, (2) policy statements and procedure manuals, (3) minutes of agency governing body meetings, (4) personnel policies and procedures, (5) personnel records, (6) training records, and (7) contracts

with persons and organizations providing services through contracts. Surveyors in Florida and Massachusetts told us that the amount of time available to conduct a survey restricts their ability to review as many patient records as they think are necessary. HCFA bases its survey budgets on the assumption that one person will complete an on-site review at a home health agency in about 2 days. For the surveys we reviewed, we found that surveyors spent from 1/2 day to 8 days on each review; 29 of the 44 reviews (66 percent) were completed within the budgeted 2 days.

The surveyors we spoke to stated they usually had some overall plan for selecting patient records, though surveyors for 30 of the surveys told us they did not use random sampling to select records. A majority said they attempted to select records that represented the various services a home health agency offered, and several said they concentrated on records of patients receiving several types of services. Most also had a goal for the number of records they would review.

Normally, surveyors did not indicate in their survey report how many records they reviewed or how many patients the agency treated; therefore, a reader could not assess how valid their conclusions were. Of the 44 survey reports we examined, 30 did not indicate how many patient records had been reviewed and 26 did not indicate the agency's patient caseload; only 5 reports contained data on both of these items. We discussed record review with the surveyors, and for 11 cases they could not recall how many records they had reviewed. For the other 33 cases, surveyors told us they had reviewed from 4 to 73 patient records; in 17 cases, the surveyors reviewed 10 or fewer records. Available information indicates that patient caseloads at these agencies ranged from about 250 to almost 17,000.

We applied the technique of acceptance sampling to 28 of the surveys we reviewed where we were able to determine the number of patient records reviewed and to estimate the patient caseload.[1] We found that in only 1 of the 28 cases could the surveyor conclude that, if no deficiencies were noted in the sample cases, at least 90 percent of the agency's records also had no deficiencies.

[1]Acceptance sampling is a type of statistical analysis that allows drawing conclusions about a universe by examining a relatively small sample of items drawn from that universe. A common application of acceptance sampling is in quality control.

In addition, using current surveyor methodologies, the records sampled may not cover all the services an agency provides. In two Massachusetts surveys, the surveyor concluded that speech therapy services the agency offered met Medicare requirements without reviewing the records of any patients receiving these services. Surveyors in the other states did not provide information on the services received by patients whose records they had reviewed.

HCFA has adopted regulations governing nursing home surveys that provide explicit guidance on survey methodology. These regulations direct surveyors to use a random process to select residents for review and a sampling plan for determining the number of residents reviewed based on the nursing home's population. The regulations also identify certain specialized treatments that may be underrepresented in a random sample and direct surveyors to select additional residents to ensure that they review at least 25 percent of the residents receiving these treatments.

The nursing home regulations also require surveyors to document the scope and results of the survey. Surveyors must use standard forms to record the survey results. Among these are forms that document the nursing home's population at the time of the survey and the number of residents reviewed. Surveyors must also prepare a standard work sheet to record the results of observations, interviews, and record reviews for each resident in the sample.

We believe that HCFA should provide additional guidance that includes instructions to surveyors on using random sampling procedures and a sampling plan that requires (1) enough records to be reviewed to yield an acceptable level of confidence in the conclusions reached about home health agency performance and (2) coverage of all services the agency offers.

Inadequate Guidance for Protecting Survey Integrity

HCFA guidance does not discuss the mechanics of the record selection process or the role the surveyor should play in it. In 28 of the 44 surveys we reviewed, the surveyor allowed agency staff to select the sample of patient records to be reviewed. Several surveyors commented that they told agency staff to select records meeting certain criteria or told the staff to select the records at random. As we discussed the wisdom of allowing agency staff to select the sample patient records, one surveyor indicated that the practice saved substantial time. Another surveyor commented that if there were any doubts that records the

staff had selected were representative, they could always personally select the records for review.

Regulations governing nursing home surveys make it clear that surveyors should control selection of the sample of residents reviewed. To ensure that home health agency surveys accurately reflect the routine performance of an agency, we believe that HCFA guidance should instruct surveyors to control the record selection process, thereby denying agency personnel the opportunity to determine which records surveyors will review and providing a more impartial examination of agency performance.

Guidance on Interpreting Medicare Requirements Is Not Clear

HCFA's State Operations Manual and the accompanying Interpretive Guidelines for home health agency surveys lack sufficient guidance on how state surveyors should (1) review branch office operations and the qualifications of contract personnel and (2) evaluate conditions they find during surveys. As a result, surveyors' opinions about the scope of their reviews varied, and surveyors interpreted the Medicare conditions of participation in different ways. JCAHO has developed agency accreditation scoring guidelines that represent one way that HCFA could promote more consistent interpretations of the conditions of participation by state surveyors.

Survey Scope Varied

Variations in survey scope can lead to differences in survey results. HCFA guidelines state that the decision to conduct on-site reviews at agency branch offices should be based on whether determining the parent organization's compliance requires on-site inspection of branch office operations. California surveyors interpreted survey procedures for home health agency branch offices in various ways. Two of the surveyors we interviewed told us they routinely perform on-site visits for the branches of all parent agencies they survey. One spent 8 days surveying a parent agency and its seven branch offices, even though the usual survey time frame was 1 to 2 days.

The scope of surveyor reviews of the qualifications of personnel employed through contracts with other agencies also varied. HCFA guidance states that agencies "should be careful not to arrange for services from agencies or organizations which furnish unqualified or untrained personnel."

Massachusetts and Pennsylvania surveyors told us that agencies must maintain files documenting that all staff employed through contracts with other organizations hold appropriate licenses or certifications and that these should be available to state surveyors for examination. One Massachusetts surveyor, however, said HCFA guidelines do not require the surveyor to verify the qualifications of contract personnel. Two California surveyors said that an agency should have documentation to satisfy themselves that such personnel have the required licenses or certifications, but that surveyors did not need to routinely verify this information.

Surveyors Interpreted the Conditions of Participation in Different Ways

Surveyors did not appear to have a clear understanding about what evidence was needed to demonstrate compliance with the Medicare conditions of participation and what conditions indicated noncompliance. For example, HCFA guidance states that home health agency personnel must have the licenses and permits required by law and that evidence should be available for the surveyor's review to show these are current. The guidance does not, however, address whether home health agencies that, in some instances, lack copies of current licenses are in noncompliance with the applicable Medicare standard. In one case, a Massachusetts surveyor found that the licenses of six registered nurses on file at an agency had expired and described this as a deficiency. At another home health agency, another Massachusetts surveyor attached to her survey report a general recommendation that the agency maintain evidence of current licensure of its personnel, but did not describe the lack of current licenses as a deficiency in the formal report.

HCFA guidance provides that a home health agency should have personnel policies that, among other things, indicate the frequency of health exams for its employees and that personnel files should reflect compliance with these policies. The guidance does not, however, address whether a lack of documentation for health exams, by itself, constituted noncompliance with the applicable Medicare standard. In several surveys conducted in California, Massachusetts, and Pennsylvania, surveyors noted that agency personnel files did not contain documentation of current health exams and concluded that the applicable Medicare standard had not been met. In two Massachusetts surveys, the surveyors found that several employee records did not contain evidence of current health examinations. The surveyors mentioned this in their reports, but did not conclude that this constituted noncompliance with the applicable Medicare standard.

HCFA requires that a health care professional supervise home health aides and review the aides' performance at least every 2 weeks. In several instances, surveyors indicated that the registered nurse should record supervisory comments about the aide's performance in the patient's clinical record. One Massachusetts surveyor, however, evaluated aide supervision by determining whether the home health agency had a written policy concerning supervision and by determining whether the registered nurse had recorded in the patient's record an initial visit to orient the aide to caring for the patient. One Pennsylvania surveyor indicated that a written policy concerning supervision of aides satisfied the supervision requirement.

Scoring Guidelines Can Promote Consistency

Scoring guidelines that JCAHO has developed for its home health agency accreditation surveys illustrate one way to help surveyors interpret home health agency standards more consistently. Surveyors assign a score for each requirement in the standards using a 5-point rating scale: a score of "1" represents full compliance; a score of "5" represents failure to meet requirements. The guidelines for assessing one area identify five data items that should be recorded in patient records. To earn a score of "1," the agency must have recorded each data item in each record reviewed. If one data item is missing or recorded in less than 50 percent of the records, the agency will receive a score of "3;" if two or more are missing, the agency will receive a score of "4."

Fiscal Intermediary and Peer Review Organization Review Results Not Provided to State Survey Agencies

HCFA relies on state survey agencies to develop information that will help determine whether home health agencies comply with the Medicare conditions of participation. In addition, two other organizations involved in home health agency reviews—fiscal intermediaries and peer review organizations—also develop information that would be useful to assess compliance with the conditions of participation. HCFA has authority to require these organizations to report to it any information needed to administer the Medicare program; the Medicare law requires peer review organizations to coordinate their activities with other review organizations. HCFA, however, has not established procedures for providing reports from fiscal intermediaries and peer review organizations to the state survey agencies or coordinating state surveys with peer review organization reviews.

Fiscal Intermediaries

Under contract with HCFA, fiscal intermediaries process and pay claims for services provided to Medicare beneficiaries by such institutional

providers as hospitals, nursing homes, and home health agencies. In processing claims, intermediaries determine whether services are covered by Medicare, whether they are medically necessary, and whether the costs billed are allowable under Medicare regulations.

Intermediaries perform reviews of selected home health agencies that address some of the same areas that are covered during state certification surveys. For example, intermediary reviewers determine whether a plan of treatment prescribes the services to be provided, whether a physician signs and periodically reviews the plan of treatment, and whether agency staff document the services they have performed. Since the beginning of fiscal year 1986, the intermediary for Massachusetts home health agencies had conducted five coverage compliance reviews for the 11 agencies whose state certification surveys we examined. In three of these five reviews, intermediary staff found deficiencies related to Medicare's conditions of participation. In one review, for example, the intermediary examined 206 visits and concluded that 42, or about 20 percent, should not be paid by Medicare. These included 38 visits where the agency had not obtained signed physician orders for treatments provided and 2 visits where agency staff had not documented in the clinical records the services they had billed. The state of Massachusetts later surveyed this agency and recommended certifying it to participate in Medicare.

Peer Review Organizations

Peer review organizations also review services provided Medicare beneficiaries to (1) evaluate the need for and appropriateness of medical services delivered, (2) assess the adequacy and quality of care, and (3) verify the diagnostic and procedural information that determines Medicare payment. These organizations review an overall random sample of cases and additional targeted cases that are selected based on concerns about coverage, overutilization, or payment.

Historically, these reviews focused on hospital services. As of August 1987, however, these organizations were required to investigate all quality-of-care complaints involving Medicare providers, including home health agencies. In April 1989, HCFA implemented a requirement that peer review organizations review the quality of home care provided to home health agency patients who are readmitted to a hospital within 31 days of discharge.

Peer review organization quality assessments use professional medical personnel, including nurse reviewers and physicians. HCFA has developed

screening criteria to assist nurse reviewers in identifying cases for further review. Regarding patients receiving home care, reviewers are directed to evaluate whether a home health agency was able to provide the services a patient required and whether agency staff notified the physician promptly of an adverse change in the patient's symptoms. HCFA's certification standards for home health agencies also address these issues. In addition, these screening criteria direct reviewers to record any evidence of injury to patients, adverse drug reactions, and indications of infections caused by medical procedures that agency staff have administered.

Rules Governing Use of Information

Under the Medicare law, HCFA has authority to require both fiscal intermediaries and peer review organizations to report any information HCFA needs to effectively administer the Medicare program. Further, the Medicare law directs peer review organizations to provide information to other public and private review organizations and authorizes disclosure of information to the state survey agencies.

HCFA regulations governing the survey process address neither state survey agency use of information developed by fiscal intermediaries and peer review organizations nor the coordination of surveys with peer review organization activities. In addition, HCFA guidance to its regional offices and to state survey agencies does not establish procedures for obtaining information from intermediaries and peer review organizations.

Limited Use of Management Tools to Assess State Surveys

HCFA has made limited use of its available management tools to assess how well the states conduct home health agency surveys. HCFA's regional offices have not fully analyzed information in its management data system for state surveys to obtain insight on how well the states conduct surveys. Further, the regional offices have not scheduled the independent federal surveys of home health agencies in such a way as to gain the fullest insight into the adequacy of state surveys.

HCFA's regional offices monitor state agency survey activities for home health agencies and other health care providers that participate in Medicare through the State Agency Evaluation Program. This program consists of routine contact with state agency staff, periodic on-site reviews of the agencies' survey operations, analysis of management data obtained from the Medicare/Medicaid Automated Certification System, and separate federal surveys of a sample of health care facilities within

the state. The regional office summarizes its findings in periodic evaluation reports that recommend operational improvements to state agencies.

Limited Use of Management Data Systems to Spot Weaknesses in State Survey Performance

Management data obtained from the Medicare/Medicaid Automated Certification System can identify state agency progress in carrying out survey activities and highlight inefficiencies and weaknesses in performing survey tasks. HCFA's regional offices use the system to determine whether the states meet HCFA goals for survey frequency and process survey documentation within established time frames. These data can also be used to compare the number and type of deficiencies identified during state surveys to national norms.

The HCFA regional offices responsible for the four states we visited used Medicare/Medicaid Automated Certification System data primarily to evaluate the administrative aspects of the survey process. Such data presented in evaluation reports covered states' timeliness in processing survey documentation and reporting survey results to the regional office. The regional offices also used the data to comment on the frequency of home health agency surveys. Two regional offices established a goal of annual surveys, while another established a goal of surveys every 2 years.

The regional offices made limited use of Medicare/Medicaid Automated Certification System data to assess substantive features of states' survey operations. None of the state evaluation reports compared the pattern of deficiencies noted in state surveys to national trends. Officials of HCFA's San Francisco regional office acknowledged that inconsistencies in interpreting Medicare requirements probably existed among the states in their region and told us that analysis of Medicare/Medicaid Automated Certification System data would help identify these inconsistencies. However, these officials also told us that the regional staff did not have time to perform the necessary analyses.

Medicare/Medicaid Automated Certification System data can provide insight into how well the state agencies perform surveys. For example, data for the second quarter of fiscal year 1987 indicated that Florida surveyors identified deficiencies in home health aide training during about 2 percent of surveys conducted during the period, compared to about 11 percent for surveys nationally. Independent federal surveys conducted in Florida during the year indicated that Florida surveyors were not identifying all aide training deficiencies. Regional office staff

found that Florida surveyors had failed to identify weaknesses in the training of home health aides at two of the eight agencies reviewed. In its evaluation report, the regional office recommended that Florida surveyors receive additional instruction on Medicare requirements governing aide training.

Limited Use of Federal Surveys to Identify Improvements Needed in State Agency Performance

Federal surveys give the regional offices additional perspective on how effectively a state's survey process operates. During fiscal year 1987, HCFA assigned its regional offices specific goals for the number of federal surveys to conduct. HCFA regional office staff may either accompany state surveyors to observe and assess their survey techniques or conduct independent surveys shortly after the state survey to compare conclusions.

The regional offices generally programmed the required number of federal surveys of home health agencies during fiscal year 1987, but did not always make effective use of these surveys. For example, all of the surveys the Philadelphia regional office performed during the year were conducted in the immediate Philadelphia area. Similarly, all of the San Francisco regional office's fiscal year 1986 federal surveys were performed in the San Francisco bay area. In these cases, the regional offices obtained little insight into the effectiveness of surveys conducted in other parts of the two states or in other states in the region.

HCFA Standards Do Not Specify Training Needed to Perform Infusion Therapy

HCFA's home health standards do not address the training of medical personnel who provide high-technology services in the home. Recent legislation directs HCFA to develop training standards for personnel who provide equipment or specified high-technology services, but does not require HCFA to develop similar training standards for all high-technology services performed in the home. We reviewed one category of high-technology services—infusion therapy. Representatives of national health organizations agreed that persons who perform infusion therapy need specialized training and experience, but the representatives' views on the specific qualifications needed differed. We visited eight agencies administering infusion therapy and found that policies concerning the qualifications of infusion therapy personnel varied. In many cases, the agencies did not document the qualifications of such personnel.

Infusion Therapy Is Provided in the Home

Over the past decade, the adaptation of sophisticated medical technologies, including respiratory care using mechanical ventilators and infusion therapies, to the home setting has expanded greatly. An increasing number of older patients receive home care services that require high-technology equipment and services. The category of infusion therapy includes nutritional support as well as intravenous administration of antibiotics, chemotherapeutic agents, and various other drugs and fluids. The home infusion therapy market has experienced considerable growth in recent years. An investment firm that has studied the market estimates that infusion therapy sales totaled $575 million in 1986 and will exceed $1.2 billion by 1990.

Several risks are associated with infusion therapy, particularly in the home setting. Patients run the risk of infection and trauma to the blood vessels and adverse reactions to compounds administered intravenously. Persons providing infusion therapy must be trained to recognize signs and symptoms of these medical problems and to take appropriate action should they appear. When the therapy is provided in the home, the patient must be trained to recognize the signs of medical problems or of mechanical problems in the infusion equipment and to maintain sanitary conditions to store and handle infusion therapy supplies. The individual providing therapy must assess whether the patient and family can be adequately trained and whether conditions in the home can provide adequate sanitation.

Infusion Therapy Personnel Need Special Training

HCFA's home health agency conditions of participation and other guidelines do not address the training and experience needed by medical personnel providing equipment or specified high-technology services in the home. As we discussed in chapter 2, HCFA is to develop training standards for all medical equipment supplier and intravenous drug therapy personnel who provide services in the home. However, standards are not required for other treatment personnel.

We discussed infusion therapy with officials of the American Medical Association, JCAHO, the National Association for Home Care, and the National League for Nursing. These officials believe that only registered nurses should perform infusion therapy and that the nurses should have recent nursing experience before being hired to perform the service in the home. Representatives of three organizations said nurses should have from 1 to 3 years of postgraduate work experience in a hospital setting. A fourth representative said they should have at least 3 months of experience in an operating room, emergency room, or critical care

unit, but also recommends hiring nurses whose education provided extensive patient care experience.

The officials we consulted also believed that home health agencies should not rely on experience or certifications to establish that nurses are qualified to perform infusion therapy, but should require them to pass a written test on infusion therapy and demonstrate their competency in a clinical setting under the supervision of an experienced clinician. One representative believed that agencies should reexamine infusion therapy nurses every 2 years.

Practices of Selected Home Health Agencies Also Varied

The eight home health agencies we visited that provided infusion therapy hired only registered nurses to perform the therapy but, with three exceptions, had not established work experience requirements that differed from the requirements for other nurses. Personnel records for 12 of a sample of 38 infusion therapy nurses they employed did not clearly document either the dates of employment or the positions held in the nurses' previous work experience. Personnel records for 21 did not indicate whether the nurse had previous infusion therapy experience. These 38 nurses told us that they had worked in positions that provided them with infusion therapy experience. In five cases, however, this experience was 5 years old when the home health agency designated them as infusion therapy nurses.

We discussed hiring practices with officials of the eight agencies we visited. Officials at two told us they qualify new infusion therapy nurses by having an experienced nurse accompany them on initial visits; one of these agencies also accepted certification by a local hospital in lieu of being accompanied on initial visits. Officials at the other six agencies told us their orientation for new infusion therapy nurses included a demonstration of competency in a clinical setting; three of the six exempted nurses with extensive infusion therapy experience from demonstrating competency. Personnel files for 12 of the 38 infusion therapy nurses at the eight agencies did not document compliance with the agency's qualification requirements; 6 other nurses appeared to have been exempted from the requirements because of previous experience.

Conclusions

HCFA relies on the findings of state surveyors to determine whether agencies comply with its standards and should be certified to participate in Medicare. HCFA guidance to state surveyors, however, has not been

adequate to ensure that surveys reflect agency performance and that surveyors consistently interpret Medicare requirements.

State surveyors have generally not used sound statistical techniques to select samples of agency records for review and have not routinely controlled the sample selection process. State surveyors should randomly select a sample that is statistically large enough to draw reliable conclusions regarding the performance of a home health agency and maintain control over the selection of records. Recently adopted regulations governing nursing home surveys would be a good model for strengthening guidance to state surveyors.

State surveyors have also interpreted Medicare requirements differently. Because of inadequacies in HCFA guidance, surveyors arrived at different conclusions regarding the scope of surveys and regarding what conditions indicate compliance with Medicare requirements. Accordingly, HCFA should provide sufficient guidance to state surveyors to assist them in determining the survey scope and in making decisions about whether agencies comply with Medicare requirements. Scoring guidelines like those used by JCAHO, which provide ways to measure the degree of compliance with home health standards, are one method of promoting more consistent compliance decisions.

In addition to the states, two other types of organizations--fiscal intermediaries and peer review organizations—examine certain home health agency services and develop information that could help state surveyors identify weaknesses in agency performance. While HCFA has authority to require these organizations to furnish information needed to administer the Medicare program, HCFA has not established procedures for state surveyors to receive information that these organizations develop.

Oversight of state survey operations by HCFA's regional offices has focused on the administrative aspects of the survey process rather than on how well the states perform surveys. The regions have made limited use of the oversight tools—analysis of Medicare/Medicaid Automated Certification System data and the results of independent federal surveys—to assess the adequacy of state surveys. Further, the documentation that state surveyors prepare does not identify the caseload of an agency or number of patient records reviewed and thus does not permit HCFA to assess the adequacy of surveys. We believe the standard reporting forms now required for nursing home surveys would form a good model for home health agency surveys.

HCFA's budgets for survey operations are currently based on the assumption that one surveyor will normally complete the on-site review at an agency in about 2 days. As a result of the changes in the survey process that OBRA requires, and the actions to strengthen the survey process that we are recommending, HCFA may need to revise these assumptions. Performing home visits on all surveys, reviewing the training of personnel who provide high-technology services, and improving procedures for sampling patient records will require more resources. HCFA should revise its budgeting process for agency surveys to consider how the size of individual agencies—and the number of patient records that must be examined to draw sound conclusions about agency performance—will affect the time and resources to complete the survey.

HCFA's standards for home health agencies do not address the training and experience of personnel who provide high-technology medical services, such as infusion therapy, in the home. The health care authorities with whom we discussed infusion therapy believe that agencies should require specific training and experience for personnel who perform these services.

OBRA and the Medicare Catastrophic Coverage Act of 1988 require training standards for all medical equipment supplier and all intravenous drug therapy provider personnel who perform high-technology services in the home. The adaptation of other sophisticated medical technologies to the home setting, however, has also expanded over the past decade. Such therapies include respiratory care using mechanical ventilators and other infusion therapies, such as nutritional support. The Medicare Catastrophic Coverage Act provisions do not address training standards for personnel who provide these therapies.

Recommendations to the Secretary of Health and Human Services

We recommend that the Secretary direct the HCFA administrator to

- establish standards for selecting samples of patient records for review during surveys that require (1) the surveyor, rather than agency staff, to control the record selection process, (2) a random sampling selection process, (3) a sampling plan that provides for selecting enough records to have sufficient confidence in the conclusions drawn about agency performance, and (4) coverage of all services the agency offers;
- develop specific guidelines to clarify the circumstances under which state surveyors should examine branch offices and the qualifications of contract personnel in order to determine agency compliance with the conditions of participation;

- conduct field tests to determine whether survey guidance is sufficient to ensure that surveyors reach consistent conclusions when conducting surveys;
- establish a procedure to give state surveyors relevant information concerning agency performance that fiscal intermediaries and peer review organizations develop;
- direct HCFA central and regional offices to increase the use of Medicare/Medicaid Automated Certification System data as a means of monitoring and comparing the performance of state survey agencies;
- adopt standard survey forms to be used by state surveyors that will provide enough information on records reviewed during the survey to allow HCFA to assess the adequacy of records review and the validity of conclusions reached;
- direct HCFA regional offices to (1) review all documentation submitted with a sample of surveys conducted by each state survey agency to determine whether the states are complying with standards for record selection and sampling and (2) discuss the results of this review in the regional offices' periodic evaluations of the state agencies; and
- revise the assumptions used in developing budgets for agency survey operations to recognize the changes in the survey process that recent legislation mandates and that we recommend. In particular, the budget process should recognize that surveys of agencies with large caseloads—at which larger samples of patient records should be reviewed—will require more time and resources.

Recommendation to the Congress

We recommend that the Congress amend the Social Security Act to require the Secretary of HHS to develop and enforce training standards for all persons who perform high-technology medical procedures in the home that present a risk to Medicare beneficiaries.

Request Letter

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United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510-6400

January 3, 1989

The Honorable Charles A. Bowsher
Comptroller General
U.S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Bowsher:

The Human Resources Division of the General Accounting Office is nearing completion of an investigation I requested on the subject of the quality of home health care, in which I asked GAO to review the Medicare survey and certification process for home health agencies. Based on that review, GAO provided several briefings that greatly assisted me in framing legislative changes to better ensure quality home health care. Subsequently, I cosponsored provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA) which significantly changed the survey and certification process, and outlined additional requirements that home health providers must meet.

Congress must now oversee the Health Care Financing Administration's implementation of these changes to ensure that the benefits of the OBRA provisions are realized. I am therefore requesting that GAO finalize its work for the Committee in this area by identifying concerns that must be addressed by regulations implementing the Act. Specifically, I ask that GAO report on problems observed in the existing survey and certification process, particularly those likely to have a continuing adverse impact on a revised process, and offer opinions on matters to consider in implementing OBRA. I would like to receive recommendations on any other ways to improve the survey and certification process -- either through legislation or regulation -- based upon GAO's completed field work.

I wish to commend your staff for the information they have provided this Committee on these issues, and look forward to receiving GAO's final report.

Sincerely,

JOHN HEINZ
Ranking Member

JH:ds

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